بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Good Retailing and Dispensing Practices

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Guideline for Good Retail and Dispensing Practices is released under the authority of

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Guideline for Good Retail and Dispensing Practice

1 Introduction

These guidelines have been developed based on Medicine Regulation R/46 (2014) and its amendment, Medicine Regulation R/49 (2016) to act as a guidance to public and private health facilities and pharmacists in relation to all processes involved in the retail and dispensing of medicines. All facilities and pharmacists must comply with legislations related to the practice of pharmacy.

2 Purpose

The purpose of this guide is to ensure that in Maldives, medicines are lawfully dispensed in both public and private health facilities. The guideline seeks to promote proper use of medicines by ensuring the right patients receive the right medicines, in the required dosage and quantities, in packaging that maintains potency and quality, with clear instructions and medicine information counselling such that adherence is improved, the occurrence of medication errors avoided.

3 Scope

The document focuses on the requirements that should be met in any medicine dispensing environment from how the premise is built, the maintenance of sanitation and hygiene, stock management and the proper handling of prescriptions to maintaining the relevant records regarding the transactions.

4 Guideline Content

4.1 Dispensing environments

The premises within which dispensing takes place must reflect quality of the service and inspire confidence. The environment must be organized so that dispensing can be performed accurately and efficiently.

4.1.1 Premises and facilities

4.1.1.1 The premises should meet the licensing requirements set by MFDA:

a. The walls, floors, and ceiling should be cleanable, impervious, and easy to clean

b. The minimum required area for dispensing is 100 ft^2 for separate pharmacies and 75 ft^2 for pharmacies within health facilities. The space available should allow for movement of staff members during dispensing whilst ensuring that the distance that dispensing staff must cover is minimized to maintain efficiency

c. Appropriate ablution facilities that are accessible to staff and patients must be available

d. Access to water

e. Smooth, impervious, easy-to-clean dispensing surfaces with adequate space

f. Access to the actual dispensing area must be restricted to authorized personnel

g. There must be adequate lighting and ventilation

h. The premises must have adequate security.

4.1.2 Sanitation and hygiene

4.1.2.1 Dispensing environments must be kept clean as most medicinal products are for internal use. The physical premises must be kept as free from dust and dirt as possible.

4.1.2.2 Maintaining a clean environment requires a regular cleaning routine, particularly for the floors, work surfaces and shelves. There must also be a daily routine of removing waste

4.1.2.3 Spillages should be wiped away immediately

4.1.2.4 Food and drink must be kept out of the dispensing area, with the refrigerator used strictly for the storage of medicines

4.1.2.5 There should be a regular routine for checking, cleaning and defrosting the refrigerator

4.1.2.6 Staff members involved in dispensing must maintain good personal hygiene and should wear protective clothing such a dust coats that can be laundered regularly

4.1.2.7 Direct contact between dispensing staff's hands and the dispensed products should be avoided

4.2 Dispensing equipment

4.2.1 Adequate equipment that is suitable for all the operations that have to be carried out must be available. The use of stainless steel and glass is recommended

4.2.2 Dispensing equipment should include, but not be limited to

a. A dispensing bench of adequate size, having a smooth, impervious working surface

b. Counting devices for tablets and capsules

c. A refrigerator equipped with a maximum and minimum thermometer

d. A suitable range of dispensing containers with separate sets for internal and external use

4.2.3 Dispensing equipment should be kept clean at all times. Cleanliness should be checked prior to each use; and the equipment should be cleaned at the end of the day.

4.3 Stock management

4.3.1 All medicines must be obtained from licensed/approved sources.

4.3.2 When receiving medicines,

a. Inspect the consignment for any damaged/broken packs. Check that all original containers are unopened and are in good condition

b. Inspect the consignment for any expired medicines

c. Separate and quarantine any defective stock from the usable stock. Dispose of these products without delay, using established disposal procedures

4.4 Storage

4.4.1 Medicine storage areas should be dry, well ventilated areas protected from direct sunlight and heat.

4.4.2 The dispensing area should possess an adequate number and type of shelves to allow orderly storage and adequate segregation of the different types of medicines to avoid mix ups. Medicines can be arranged according to pharmacotherapeutic category, alphabetical order or according to dosage forms.

4.4.3 Do not store anything directly on the floor. Use pallets if required

4.4.4 Adhere to the manufacturer's storage conditions when storing products in the dispensary

4.4.5 Stock containers must be kept closed except when in use and products that require cold storage in appropriate temperature controlled areas.

4.4.6 Regular monitoring and maintenance of records with respect to the refrigerator temperature should be an established procedure

4.4.7 The dispensary must possess a lockable, fixed cabinet for controlled substances namely Narcotics and scheduled Psychotropic Substances.

4.4.8 Flammable substances must be kept separately.

4.5 Stock control

4.5.1 Establish and maintain a stock control system to minimize wastage due to expiry, or unnecessary over- or under-stocking. It is good practice to establish minimum order quantities

4.5.2 Store and manage products according to the 'First Expiry, First Out' (FEFO) principle with the 'First in, First Out' (FIFO) being a secondary control mechanism where the expiry dates are the same

4.5.3 Periodic stock reconciliation shall be performed, by comparing the actual and recorded stocks

4.5.4 Stocks shall be regularly checked and any expired medicines shall be removed and quarantined.

4.6 Principles and processes of Good Dispensing Practice

4.6.1 Principles of good dispensing

4.6.1.1 Adherence to Good Dispensing Practices is vital in ensuring that medicines are dispensed correctly, and any potential or real errors which may occur are detected and rectified before the medicines reach the patient.

4.6.1.2 Proper record keeping is an essential part of dispensing as it facilitates good management and monitoring of the services provided. Such records can be used if the need arises to trace patients dispensed with a particular medicine.

4.6.1.3 All medicines should be dispensed with adequate and proper information and counselling. Although basic knowledge is obtained through formal pharmacy training, additional information can be obtained from various primary, secondary and tertiary sources

4.6.2 The dispensing process

4.6.2.1 In this guide, the dispensing process has been broken down to eight (8) major steps:

4.6.2.2 Receiving and validating the prescription

4.6.2.3 On receipt of a prescription, the dispenser should confirm that the prescription is authentic by checking the legal requirements.

4.6.2.4 A legal prescription should be legibly written or typed and signed by an authorized prescriber

4.6.2.5 The prescription should have the following information:

a. Name

b. Patient details, including address; and the age and body weight if the patient is below 12 years of age

c. Date of prescription

d. Dose

e. Frequency

f. Doctor's name and signature

g. Stamp

4.7 Understanding and interpreting prescription

4.7.1 The person receiving the prescription should check for:

a. Dose, frequency, and duration

b. Drug interactions, medicine duplications, polypharmacy, inappropriate medicine therapy and contra-indications

c. Allergies

d. Unusual usage and suspected misuse or abuse

4.7.2 Any doubt regarding the prescription or any suspicion of error should be discussed or consulted with other pharmacists or the prescriber without arousing doubts or fears in the patient. Where feasible and practically possible (e.g. prescriber is on site), the incomplete or missing details or correction should be made by the prescriber. Where this is not possible, authorization to make the change can be obtained from the prescriber by telephone in which case the amendments must be repeated back to the prescriber to ensure accuracy. The amendments should be documented and preferably endorsed "prescriber contacted".

4.7.3 Correctly interpret any abbreviations used by the prescriber. Every word/abbreviation has a meaning – do not assume an illegible or confusing word or abbreviation is unimportant.

4.7.4 For partial medicine supply, ensure that the second or subsequent supply does not exceed the quantity for the duration prescribed.

4.7.5 All calculations should be double-checked by the dispenser or counter-checked by another staff member

4.7.6 Selecting the medicine

4.7.6.1 When selecting the medicine to be dispensed, prevent any medication error by establishing an appropriate system to ensure the correct medicine is selected. Pick the medicine by reading the label at least twice and cross-checking the medicine name and strength against the prescription.

4.7.6.2 Check the expiry date of the selected pack to ensure that the medicine remains unexpired for the duration of the supply course.

4.7.6.3 Extemporaneous preparations should only be prepared if there is no equivalent product available commercially or the product has to be compounded based on the patient's needs. Ingredients for compounding must be sourced from recognized pharmaceutical suppliers

4.7.7 Packing and labelling the medicine

4.7.7.1 Medicines should be dispensed in original packaging as far as is possible.

4.7.7.2 Medicines should be packed into a clean, dry container, such as a bottle or plastic dispensing envelope, which will not compromise the quality of the product after dispensing

4.7.7.3 Any prepackaging of frequently used medicines must be adequately controlled. The prepackaging operations and area must be clean and separate from other pharmacy activities. Only one medicine should be prepacked at a time.

4.7.7.4 All dispensed medicines should be labeled according to the requirement stated by the medicine regulation.

4.7.7.5 Labels should be unambiguous, clear, legible, and indelible. The label should uniquely identify the contents of the container and ensure that the patient has clear and concise information about the use of the medicine

4.7.7.6 It is advisable for labels to be printed. If handwritten, labels should be neat and legible with clear instruction on use.

4.7.7.7 Label should contain (as per medicine regulation)

a. Name of the medicine

b. Dosage form, strength and quantity

c. Direction for use (frequency and duration)

d. Date of supply

e. Medicines for external use should be labeled with the word

f. "Not to be taken" or for external use only in Dhivehi and or English.

g. Special precautionary (labels should be used where necessary)

h. (Eg: - Complete the course for antibiotics may cause drowsiness for sedating drugs)

4.7.8 Storage condition

4.7.8.1 Name and address of dispensing institution

4.7.8.2 The Patient Information Leaflet (PIL) should be provided, where available

4.7.8.3 Check the prescription and the filled medicine to ensure that the filled medicine correlates with the prescription

4.7.9 Counterchecking

4.7.9.1 Although this can be done as a self-check, counterchecking should preferably be done by a second person

4.7.9.2 The final check should include reading and interpreting the prescription before looking at the dispensed medicines; checking the appropriateness of doses and drug interactions; checking the identity of the medicine dispensed; checking the labels and counter-signing the prescription.

4.7.10 Recording

4.7.10.1 Each sale or supply of medicine must be recorded in a prescription book which can be maintained as a manual or electronic record.

4.7.10.2 The date of supply, serial number of the entry of the prescription, name of the medicine and quantity supplied; and name and address of the patient must be recorded in respect of each sale or supply

4.7.11 Providing patient information and instructions

4.7.11.1 Where necessary, provide medication counselling to ensure proper use of the medicines dispensed. It is encouraged to counsel patients with chronic conditions especially of they are on multiple medications.

4.7.11.2 Structure the information to meet the needs of the individual patient

4.7.11.3 Use questions and answers to check patient understanding

4.7.12 Prescription filing

4.7.12.1 Prescriptions should be filed in an orderly manner and labelled to ensure easy retrieval

4.7.12.2 Prescriptions and dispensing records should be kept in a secure place that is easily accessible only to authorized personnel

4.7.12.3 Records must be stored and be available for inspection for two years after the date of supply

5 References

- Guide to Good Dispensing Practice: Pharmaceutical Services Division, Ministry of Health, Malaysia
- Manual for Medicines Good Dispensing Practice
- Ensuring Good Dispensing Practices: Pharmaceutical Management, Management Sciences for Health